Change in correspondence address.

Applicants note that a Revocation and Substitute Power of Attorney incorporating a change in correspondence address was filed on April 30, 2001, a copy of which is enclosed. In accordance with the instructions provided therein, **please direct all future correspondence regarding the subject application to CUSTOMER NUMBER 22798, that is:**

22798

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Election/Restriction.

Pursuant to a restriction requirement previously made final, Applicants have canceled non-elected claims 23-44 with entry of this amendment. Please note, however, that Applicants reserve the right to file subsequent applications claiming the canceled subject matter and the claim cancellations should not be construed as abandonment or agreement with the Examiner's position in the Office Action.

35 U.S.C. §112, First Paragraph.

Claims 1, 6-19, 45, 46, and 58-63 were rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter that was not described in the specification in such a way as to reasonably convey to one of skill in the art that the inventors had possession of the claimed invention at the time the application was filed. Applicants traverse.

As stated in *Union Oil Co. of California v. Atlantic Richfield Co.*, 54 USPQ2d 1227 (CAFC 2000), the "written description requirement does not require the applicant 'to describe exactly the subject matter claimed, [instead] the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.'" *Id.* at 1232 (citation omitted). The primary purpose of this requirement is to ensure that the specification clearly conveys to one skilled in the art what the applicant regarded as his or her invention when the application was filed. This requirement serves the public policy of limiting the ability of an applicant to later claim subject matter that, while enabled by the specification, was not identified in the specification as the applicant's invention. Thus, as the Federal Circuit recently reiterated in *Purdue Pharma L.P. v. Faulding Inc.*, "[a]dequate description of the invention guards against the inventor's overreaching by insisting that he recount his

invention in such detail that his future claims can be determined to be encompassed within his original creation." *Purdue Pharma L.P. v. Faulding Inc.,* 56 USPQ2d 1481, 1487 (Fed. Cir. 2000) (quoting *Vas-Cath, Inc. v. Mahurkar*, 19 USPQ2d 1111, 1115 (Fed. Cir. 1991) and *Rengo Co. v. Molins Mach. Co.*, 211 USPQ 303, 321 (3d Cir. 1981)).

The description requirement **does not**, however, include a requirement that a patent applicant actually reduce the invention to practice and describe this reduction to practice in the application. **Thus, a patent applicant need not have actually produced a composition in order to claim the composition.** The often-quoted test for satisfaction of the description requirement is that the application must contain sufficient disclosure to make it clear to one skilled in the art that the applicant was "in possession" of the subject matter claimed. This language suggests that the applicant must have actually made the invention. **But this interpretation is clearly incorrect, given that the law recognizes that a patent applicant can constructively reduce an invention to practice by describing an invention in a patent application. Furthermore, requiring a patent applicant to describe an actual reduction to practice in the specification would be inconsistent with the well-settled rule that working examples are not required.** *See Ex parte Nardi*, 229 USPQ 79, 80 (1986).

Nor does the description requirement mandate that the description in the specification communicate to one skilled in the art that the patent applicant could have actually reduced the invention to practice at the time of filing. This is the province of the enablement requirement. Thus, the inquiry as to whether the application contained sufficient disclosure to make it clear to one skilled in the art that the applicant was in possession of the subject matter claimed does not turn on whether the applicant actually practiced the invention or clearly could have done so at the time of filing. Rather, the description requirement inquiry must turn on whether the applicant adequately pointed out what was invented.

Applicants submit that to determine if the specification adequately describes the recited product produced by the recited process, it is necessary to consider only whether the structural, functional, and process elements, and the relationships among them, are set forth in the application so that one of skill would recognize that the application describes the invention recited in the claims.

In instant case, the pending claims are drawn to isolated nucleic acids that hybridize to the referenced nucleic acids under defined (stringency) conditions. In other words, the nucleic acids are defined in functional terms.

This is analogous to the situation in *Union Oil Co. v Atlantic Richfield et al.* 208 F.3d 989 (Fed. Cir. 2000). In this case, a patent directed to gasoline formulations described the gasoline in terms of final properties (*e.g.* vapor pressure, distillation point, *etc.*). The specification described relationships among gasoline characteristics and fuel emissions, **but did not provide explicit formulations**. The Federal circuit held that the patent met the description requirement stating that:

> Appellant refiners assert that the specification does not describe the exact chemical component of each combination that falls within the range claims of the '393 patent. **However, neither the Patent Act nor the case law of this court requires such detailed disclosure.** See *In re Hayes Microcomputer Prods., Inc.*, 982 F.2d 1527, 1533, 25 U.S.P.Q.2D (BNA) 1241, 1245 ("[The applicant] does not have to describe exactly the subject matter claimed."); Vas-Cath, 935 F.2d at 1566 ("ranges found in applicant's claims need not correspond exactly to those disclosed in [the specification]; **the issue is whether one skilled in the art could derive the claimed ranges from the disclosure.**"). **[emphasis added]**

Nucleic acids that specifically hybridize to the referenced nucleic acids under stringent conditions are readily recognized and identified.

Moreover, the situation is analogous to the antibody art where antibodies or epitopes are often characterized simply by their binding specificity with no structural information whatsoever. (*See, e.g.,* U.S. patent 6,291,239 which claims "[a] monoclonal antibody (FE8) against human complement receptor type 2 (CR2, CD21) which is able to substantially remove C3-derived fragments already attached to CR2, in particular C3dg from CR2 at temperatures of 25°C and above", U.S. Patent 6,258,364 which claims "[a]n isolated carbohydrate epitope that binds to a monoclonal antibody expressed by Hybridoma cell line HB-12144.", U.S. Patent 6,166,168 which claims "[a] monoclonal antibody which binds specifically to a human-Th2-specific protein comprising the amino acid sequence set forth in SEQ ID NO:6", and so forth.). The Patent Office clearly recognizes that it is possible and acceptable to claim genera of molecules (*e.g.* antibodies) simply by their binding specificity and such claims meet the description requirement.

There is no intrinsic difference between a genus of antibodies claimed simply by a binding specificity and a genus of nucleic acids similarly claimed. Moreover, the specific structure of the claimed nucleic acid is envisaged far more readily than the chemical structure of the antibodies. In both cases, one of ordinary skill in the art would appreciate that the Applicants "possess" the claimed invention at the time of filing.

In addition, Applicants note that:

> [T]o provide effective incentives, claims must adequately protect inventors. To demand that the first to disclose shall limit his claims to what he has found will work or to materials which meet the guidelines specified for "preferred" materials in a process such as the one herein involved would not serve the constitutional purpose of promoting progress in the useful arts. *In re Goffe*, 191 USPQ 429, 431 (CCPA 1976).

In view of the foregoing, the rejection of claims 1, 6-19, 45, 46, and 58-63 under 35 U.S.C. §112, first paragraph, on description grounds is improper and should be withdrawn.

35 U.S.C. §103(a).

Claims 1, 6, 8, 10, 12, 14, 16, 18, 23, 45, and 46 were rejected under 35 U.S.C. §103(a) as allegedly obvious in light of various GenBank Accession Numbers (ESTs) as summarized below in **Table** 1, taken with Matthews and Kricka (1988) *Analytical Biochem.*, 169: 1-25.

Table 1. Summary of specific rejections correlating Accession Numbers with claimed sequences.

Office Action Paragraph	GenBank Accession No.	CLAIM SEQ ID NO.
4	N32481, N93893, or G11697	SEQ ID NO:4
5	H16953, I6954, or H12950	SEQ ID NO:5
6	H40682	SEQ ID NO:6
7	G24710, or G25553	SEQ ID NO:7
8	N7851	SEQ ID NO:8
9	N70546	SEQ ID NO:9
10	WO5407	SEQ ID NO:10

In particular the Examiner alleged that the cited Accession Numbers teach polynucleotide sequences that would hybridize to the indicated sequences under stringent conditions. The Examiner acknowledged that the cited Accession Numbers do not teach labeled sequences and cited Matthews as allegedly teaching methods for labeling polynucleotide sequences. With regard to motivation, the Examiner simply alleged that "radiolabeling of DNA to be used as a probe for hybridization is routine in

the art" and that "sequences that hybridize to the disclosed SEQ ID NOs are known in the art." Applicants respectfully traverse.

A) SEQ ID NOS: 9 and 10 (claims 1, 16, 18, 23, and 45-46).

With respect to claims 1, 16, 18, 23, and 45-46, in so far as they recite SEQ ID NOS 9 or 10, Applicants submit that Applicants invented the claimed invention before the publication date of the cited references. Upon an indication of otherwise allowable subject matter, Applicants will submit a declaration under 37 C.F.R. §1.131 swearing behind references N70546 and WO5407.

B) SEQ ID NOS: 4, 5, 6, 7, and 8 (claims 1, 6, 8, 10, 12, 14, 23, 45-46)

The Examiner is reminded that an obviousness rejection requires a teaching or suggestion to modify the references in the manner indicated by the Examiner. As stated by the Court of Appeals for the Federal Circuit:

> Our case law makes clear that the best defense against hindsight-based obviousness analysis is the rigorous application of the requirement for a showing of a teaching or motivation to combine the prior art references. See Dembiczak, 175 F.3d at 999, 50 USPQ2d at 1617. **"Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability--the essence of hindsight." Id.** [emphasis added] *Ecolochem, Inc. v Southern-California Edison Company,* __ USPQ2d ___ (Fed. Cir. 2000)

See also:

> The mere fact that the prior art may be modified in the manner suggested by the Examiner **does not** make the modification obvious unless the prior art suggested the desirability of the modification. [emphasis added] *In re Fritch*, 23 USPQ 2d 1780, 1783-1784 (Fed. Cir. 1992)

> **The test is not whether one device can be an appropriate substitute for another**. See *Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1383, 231 USPQ 81, 93 (Fed. Cir. 1986)* ("Focusing on the obviousness of substitutions and differences instead of on the invention as a whole, as the district court did in frequently describing the claimed invention as the mere substitution of monoclonal for polyclonal antibodies in a sandwich assay, was a legally improper way to simplify the difficult determination of obviousness."). **The district court must make specific findings establishing why it was "apparent"** to use the screw anchor of the Fuller and Rupiper method in combination with the metal bracket as used in the Gregory patents. [emphasis added].

In making her *prima facie* rejection under §103(a), the Examiner has failed to establish, with particularity, why it was apparent to label the nucleic acids recited in the presently pending claims while ignoring the thousands of other sequences present in GenBank. Simply alleging that the nucleic acids are known and that labeling is known is not making specific findings why it was apparent to label specifically the nucleic acids recited in the pending claims. **The issue is not whether or not labeling of nucleic acids is known, but rather what particular teaching would lead one of skill in the art to label the nucleic acids recited in the pending claims.**

As stated by the Federal Circuit:

> A critical step in analyzing the patentability of claims pursuant to section 103(a) **is casting the mind back to the time of invention**, to consider the thinking of one of ordinary skill in the art, **guided only by the prior art references and the then-accepted wisdom in the field**. *See Dembiczak* , 175 F.3d at 999, 50 USPQ2d at 1617 . **Close adherence to this methodology is especially important in cases where the very ease with which the invention can be understood may prompt one "to fall victim to the insidious effect of a hindsight syndrome wherein that which only the invention taught is used against its teacher**." Id. (*quoting W.L. Gore & Assocs., Inc. v. Garlock, Inc.* 721 F.2d 1540, 1553, 220 USPQ 303, 313 (Fed. Cir. 1983)). [emphasis added] (*In Re Werner Kotzab,* 217 F.3d 1365, 55 USPQ2d 1313, ____ (Fed. Cir. 2000)

In the instant case, lacking the teaching provided in the specification, there is nothing to lead one of ordinary skill to select the ESTs identified by the Examiner from the thousands of ESTs in GenBank and to label those ESTs.

The descriptive information published along with each cited EST **does not** provide any information about the use or putative significance of the respective nucleotide sequence. Moreover, the Examiner has failed to identify any teaching or suggestion in the cited art that would lead one of skill to the specific sequences recited in the pending claims.

Indeed, the only teaching that leads one of skill specifically to these sequences is the teaching offered in the present application. The Examiner is, in effect, taking the present inventors' own disclosure "as a blueprint for piecing together the prior art to defeat patentability--the essence of hindsight". Without the teaching provided in the present specification there is nothing in the art that would lead one of skill to produce the presently claimed nucleic acids. Lacking such motivation, the

Examiner has failed to make a *prima facie* case of obviousness and accordingly, the rejection of claims 1, 6, 8, 10, 12, 14, 16, 18, 23, 45, and 46 were rejected under 35 U.S.C. §103(a) should be withdrawn.

Obviousness-Type Double Patenting.

Claims 1m 6-19, 23, and 45-67 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting over copending application number 08/785,532.

Claims 1m 6-19, 23, and 45-67 were rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-9 of U.S. Patent 5,892,010. Applicants will provide a Terminal Disclaimer upon an indication that the claims are otherwise allowable.

In view of the foregoing, Applicants believes all claims now pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If a telephone conference would expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (510) 337-7871.

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Respectfully submitted,

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APPENDIX A

VERSION WITH MARKINGS TO SHOW CHANGES MADE IN 08/731,499 WITH ENTRY OF THIS AMENDMENT

In the specification:

No change.

In the claims:

No change.